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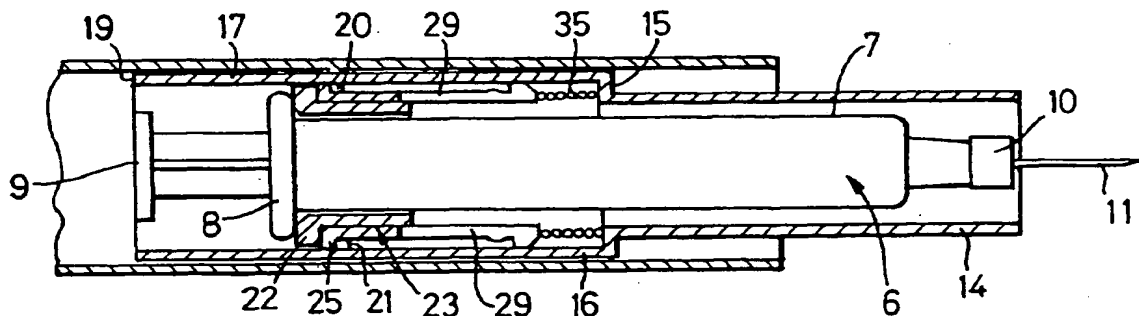
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPROVEMENTS RELATING TO INJECTION DEVICES



(57) Abstract: When the injection device is applied to a patient's skin and a plunger (9) is pressed, the entire syringe and a carrier (23) move forwards in relation to a barrel (1) such that ribs (32) on the carrier (23) snap past a rib (21) on a shroud. The syringe is arrested by flanges (25) coming up against the rib (21), and a spring (35) is compressed and a needle (11) is fully projected. Further pressing on the plunger (9) ejects the dose. The needle shroud (14) is kept at the rearward position by its firm engagement around the injection area. On withdrawal of the device, the shroud (14) is pushed forwards by the spring (35) to protect the needle (11). This draws fingers (17 and 18) through gaps (20) in the ribs (21), the fingers (18) being forced to bend towards the fingers (17) as the divergence takes effect. Once the fingers (18) have passed the rib (21), they spring back to their natural straight condition to abut the rib (21) if any attempt is made to push the shroud (14) backwards again. At the same time barbs (19) on the ends of the fingers (17) re-engage the rear end of the syringe carrier (23), whose flanges (25) are up against the rib (21), thus thwarting any attempt that may be made to pull the needle shroud clear of the barrel. The shroud (14) is therefore trapped, the needle (11) safely within.

WO 03/013632 A2

Improvements relating to Injection Devices

This invention relates to medical injection devices. It is concerned with those in which a syringe is within a housing, initially fully encased, but once the housing is uncapped it can be moved forwards for the needle to be projected and for the dose to be administered. The user holds the housing rather than the syringe itself.

It is known to have a needle shroud carried by the housing which after injection can be shifted to a position concealing the needle. It is important that such a shroud should not then be moved, risking re-exposure of the needle. It is the aim of this invention to provide a simple and reliable way of locking such a shroud automatically to its housing.

According to the present invention there is provided an injection device for a syringe, the device comprising a housing for the syringe with a forwardly biased needle shroud at its leading end capable of movement between forward and rearward positions, the syringe during injection being moved forwards to project its needle beyond the shroud in its rearward position, and the shroud, moved to its forward position concealing the needle after injection, being prevented from reversion to its rearward position by snap-engagement with part of the housing.

Preferably, the shroud will telescope into a barrel-like housing. It can have at least one rearwardly extending finger that extends past an abutment within the housing, that finger being flexed as the shroud moves forwards for its tip to move past the abutment. Thereupon the finger springs back to its natural configuration with its tip in front of the abutment, thereby preventing the shroud

moving backwards.

Conveniently, this flexing of the finger will be circumferential, in which case there must be means for preventing the shroud rotating with respect to the housing if those two members are bodies of revolution. These means may be combined with means for preventing complete withdrawal of the shroud from the housing. A further, longer finger may be associated with and divergent from the or each first finger, both fingers of a pair passing through a common gap in the abutment within the housing. This further finger may have a hook formation at its rear, free end, and this will effectively engage behind the abutment when the shroud reaches its forward position. As it moves towards that, the fingers are squeezed together by the sides of the gap until the first, shorter finger clears the gap and springs away from the second, longer finger.

The abutment within the housing may also serve to locate a carrier for the syringe before injection, and it can also provide a limit to the forward movement of the capsule of the syringe.

In the preferred form, the housing will have a cap, removable forwardly for use of the device, with a tubular portion that extends back into the housing to co-operate with the carrier and prevent that disengaging from the abutment. In other words, it keeps the carrier located in its pre-injection position and prevents premature operation. But once the cap is removed, the carrier will be capable of disengagement from the abutment.

For a better understanding of the invention, one embodiment will now be described, by way of example, with reference to the accompanying drawings, in which:

Figures 1 to 6 are axial sections of an injection device showing it in various stages from pre-use to post-use,

Figure 7 is a perspective view of a needle shroud forming part of the injection device,

5 Figure 8 is a cross-section on the line VIII-VIII of Figure 3,

Figure 9 is a perspective view of a syringe carrier forming part of the device, and

Figure 10 is a cutaway perspective view of the injection device.

10 The injection device to be described is intended to form part of an auto-injection system. A spring-loaded drive mechanism will be attached to the rear end of the device, and when released or fired it will act on the syringe within the device to thrust that forward and eject the dose. Such drive mechanisms are known and therefore they are not illustrated and are not described in detail.

15 The injection device has a cylindrical barrel 1 initially closed at its leading end by an elongate cap 2. This has a relatively short outer tubular section 3 which plugs into the barrel 1, being limited by an annular rib 4, and a much longer re-entrant tubular section 5 which initially extends back into the barrel to encase about three quarters the length of a syringe 6. This is of conventional form with a capsule 7 having a rear end flange 8 beyond which a plunger 9
20 extends, while at the reduced leading end there is a needle assembly 10 with the needle 11 concealed within a sheath 12. The interior of the re-entrant portion 5 has an annular rib 13 of triangular section which, on assembly, can snap past the enlarged base of the sheath and engage behind it.

Surrounding the forward half of the re-entrant portion 5 in the initial state

of the device is a tubular needle shroud 14. This steps out at a shoulder 15 into a short rear tubular section 16, from whose free rim there project rearwardly two pairs of fingers 17 and 18, one of which is best seen in Figure 7. The finger 17 is the longer, is axially parallel, and terminates at its rear end in a bifurcation with outwardly projecting barbs 19. The shorter finger 18 has a plain end, and it diverges circumferentially slightly from the finger 17. Initially, both these pairs of fingers extend through diametrically opposed gaps 20 in an annular rib 21 on the inside of the barrel 1, as shown in the detail of Figure 8. The plastics material of which the needle shroud 14 is made allows the fingers 18 to be flexed towards the associated fingers 17, to allow them to pass through the gaps 20 on assembly.

Surrounding the rear end of the capsule 6, with the intermediary of a resilient bush 22, there is a syringe carrier 23, as best seen in Figure 9. This has a short cylindrical portion 24 with two outward almost semi-circular flanges 25 at its rear end between whose ends there are studs 26 creating gaps 27 and 28. Two pairs of diametrically opposed fingers 29 and 30 project from the forward end of the portion 24, the fingers 29 being wider in the circumferential direction than the gaps 20 and externally terminating in angled teeth 31 with a rounded rib 32 a short distance to the rear of each tooth 31. The bevel or angle on the forward side is to aid assembly, when the teeth are snapped past the rib 21. The fingers 30 of the other pair are somewhat narrower, slightly longer, and terminate in inward flanges 33 with a rebate 34 in the outside of each corner between finger 30 and flange 33. The radial faces of these rebates 34 are coplanar with the ends of the fingers 29. A helical spring 35 has its rear end

located by these rebates 34 and also bears against the ends of the fingers 29 while its forward end acts against the shoulder 15. As assembled, the fingers 29 and 30 overlap the rear end of the re-entrant portion 5, and the teeth 31 and ribs 32 engage around the rib 21 on either side of the gaps 20. The ends of the
5 fingers 17 extend through the gaps 27 and their barbs 19 hook behind the flanges 25 and studs 26 of the syringe carrier 23. The tips of the fingers 18 are opposite the gaps 28 and the spring 35 is relaxed.

To prepare the device for use, the cap 2 is removed as shown in Figures 2 and 3. By virtue of the rib 13 engaging behind the sheath 12, that is drawn off
10 the needle 11. During the initial freeing of the sheath 12 the rear end of the portion 5 still overlaps the fingers 29, thereby preventing them from flexing inwards and keeping the ribs 32 engaged with the rear side of the rib 21. The carrier 23 is not therefore tugged forwards with the sheath 12. But once that sheath is freed from the needle assembly 10, the internal backing of the fingers
15 29 by the portion 5 is no longer there, making it possible for those fingers to flex inwardly.

Also initially, the needle shroud 14 cannot move backwards because the rear end of the portion 16 is up against the rib 21, and it cannot move forwards since the barbs 19 are hooked behind the flanges 25 and studs 26 of the
20 immobilised syringe carrier 23.

The device is then applied to the patient's skin and the plunger 9 pressed. This pushes the entire syringe and the carrier 23 forwards in relation to the barrel 1 by virtue of the effective solidity of the dose within the capsule, the ribs 32 snapping passed the rib 21 at the commencement of this movement. The

syringe is arrested by the flanges 25 coming up against the rib 21, the spring 35 now being compressed and the needle 11 fully projected. Further pressing on the plunger 9 ejects the dose. The needle shroud 14 is kept at its original rearward position by its firm engagement around the injection area.

5 On withdrawal of the device, the needle is protected by the shroud 14 being pushed forwards by the spring 35 to the position shown in Figure 6. This draws the fingers 17 and 18 through the gaps 20, the fingers 18 being forced to bend towards the fingers 17 as the divergence takes effect. But once the fingers 18 have passed the rib 21, they spring back to their natural straight condition.

10 This means that they will abut the rib 21 if any attempt is made to push the shroud 14 backwards again. At the same time the barbs 19 re-engage the rear end of the syringe carrier 23 whose flanges 25 are up against the rib 21, thus thwarting any attempt that may be made to pull the needle shroud clear of the barrel. The shroud 14 is therefore trapped, the needle 11 safely within.

Claims

1. An injection device for a syringe, the device comprising a housing for the syringe with a forwardly biased needle shroud at its leading end capable of movement between forward and rearward positions, the syringe during injection being moved forwards to project its needle beyond the shroud in its rearward position, and the shroud, moved to its forward position concealing the needle after injection, being prevented from reversion to its rearward position by snap-engagement with part of the housing.

2. An injection device according to claim 1, wherein the shroud telescopes into a barrel-like housing.

3. An injection device according to claim 1 or claim 2, wherein the shroud has at least one rearwardly extending finger that extends past an abutment within the housing, that finger being flexed as the shroud moves from the rearward to the forward position, for its tip to move past the abutment, the finger being located to spring back to its natural configuration with its tip in front of the abutment, thereby preventing the shroud moving backwards, after the shroud has moved back to the forward position.

4. An injection device according to claim 3, wherein flexing of the finger is circumferential.

5. An injection device according to claim 4, wherein anti-rotation means is provided for preventing the shroud rotating with respect to the housing if those two members are bodies of revolution.

6. An injection device according to claim 5, wherein the anti-rotation means

is combined with means for preventing complete withdrawal of the shroud from the housing.

7. An injection device according to any one of claims 3 to 6, wherein a further, longer finger is associated with and divergent from the or each first finger, the first and further fingers of the pair passing through a common gap in the abutment within the housing.

8. An injection device according to claim 7, wherein the further finger has a hook formation at its rear, free end, which will effectively engage behind the abutment when the shroud reaches its forward position.

9. An injection device according to any one of claims 3 to 8, wherein the abutment within the housing serves to locate a carrier for the syringe before injection.

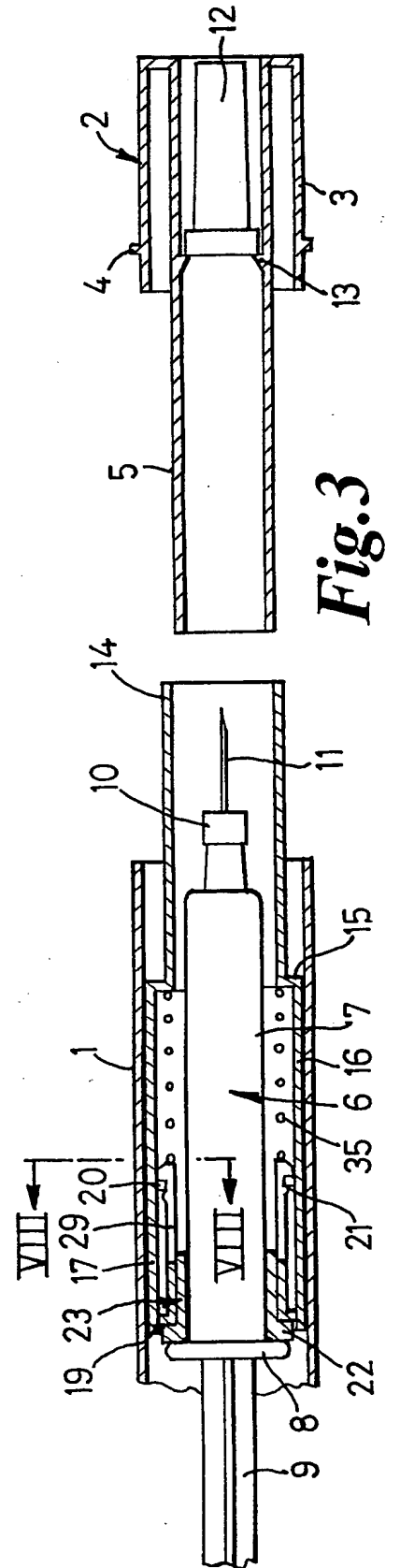
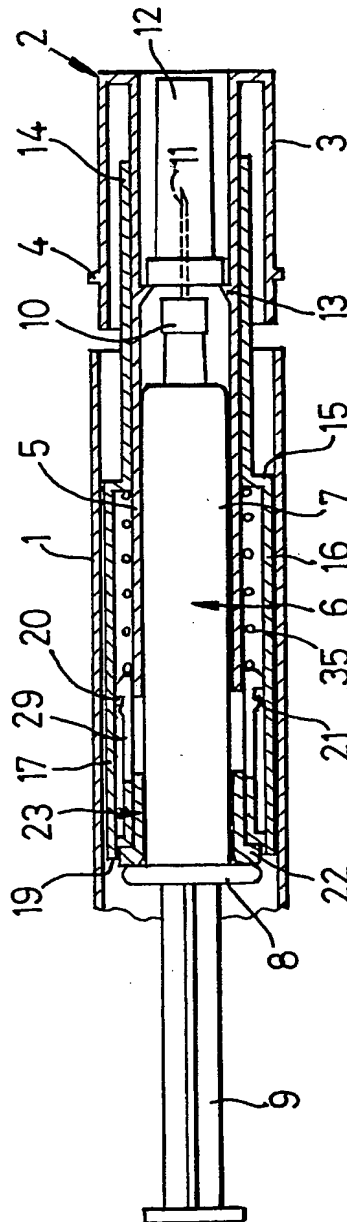
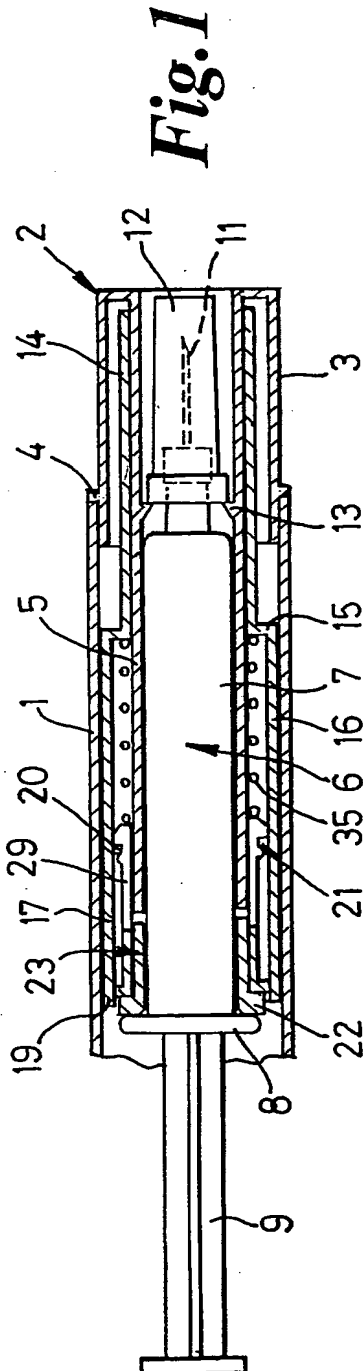
10. An injection device according to claim 9, wherein the abutment within the housing provides a limit to the forward movement of the capsule of the syringe.

11. An injection device according to claim 9 or claim 10, wherein the housing has a cap, removable forwardly for use of the device, with a tubular portion that extends back into the housing to co-operate with the carrier and prevent that disengaging from the abutment.

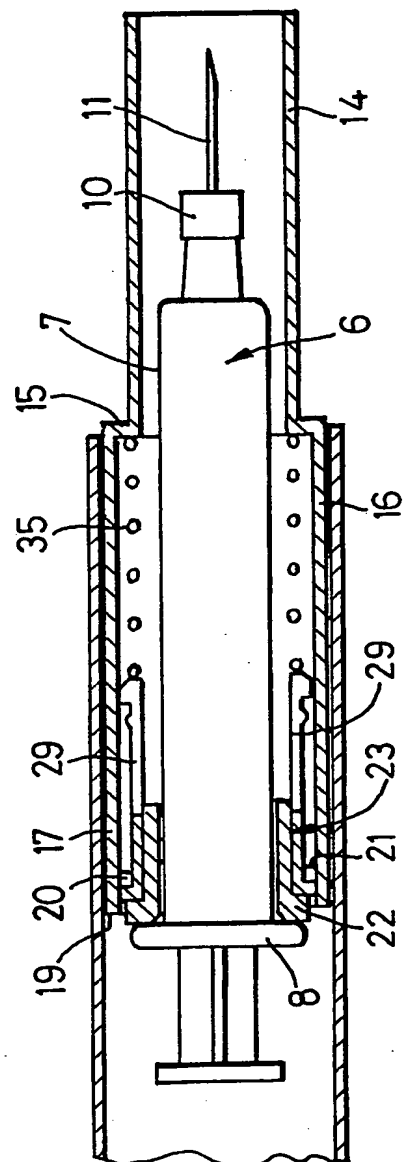
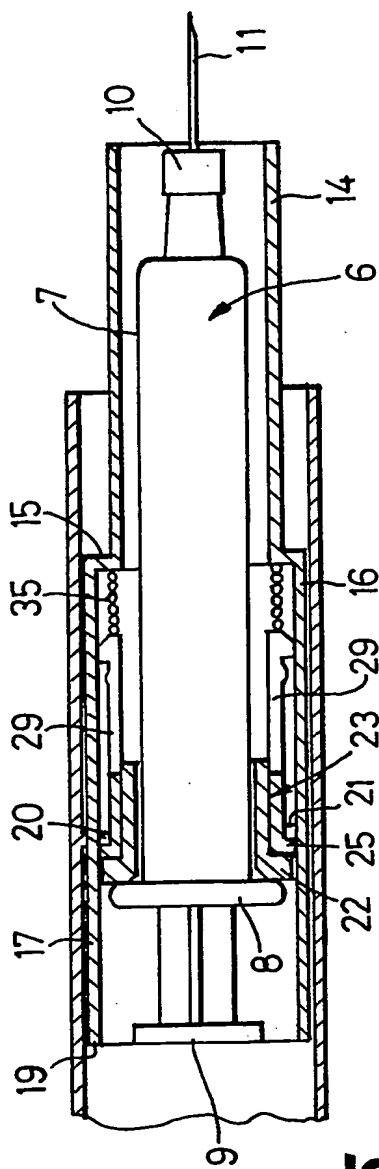
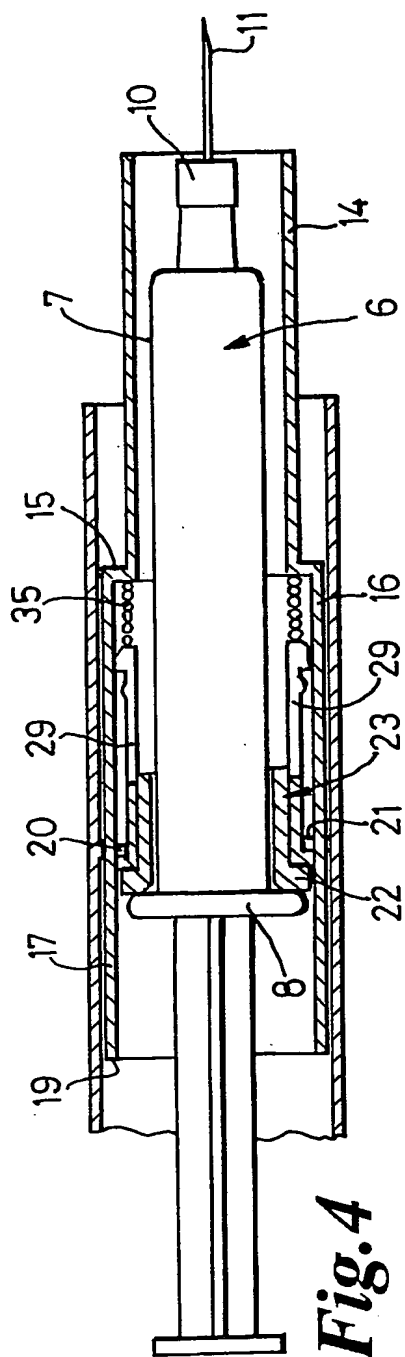
12. An injection device for a syringe, substantially as herein described with reference to the accompanying drawings.

13. Any novel combination of features of an injection device for a syringe, as described herein and/or as shown in the accompanying drawings.

1/4



SUBSTITUTE SHEET (RULE 26)



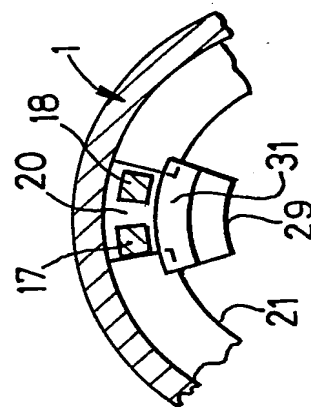
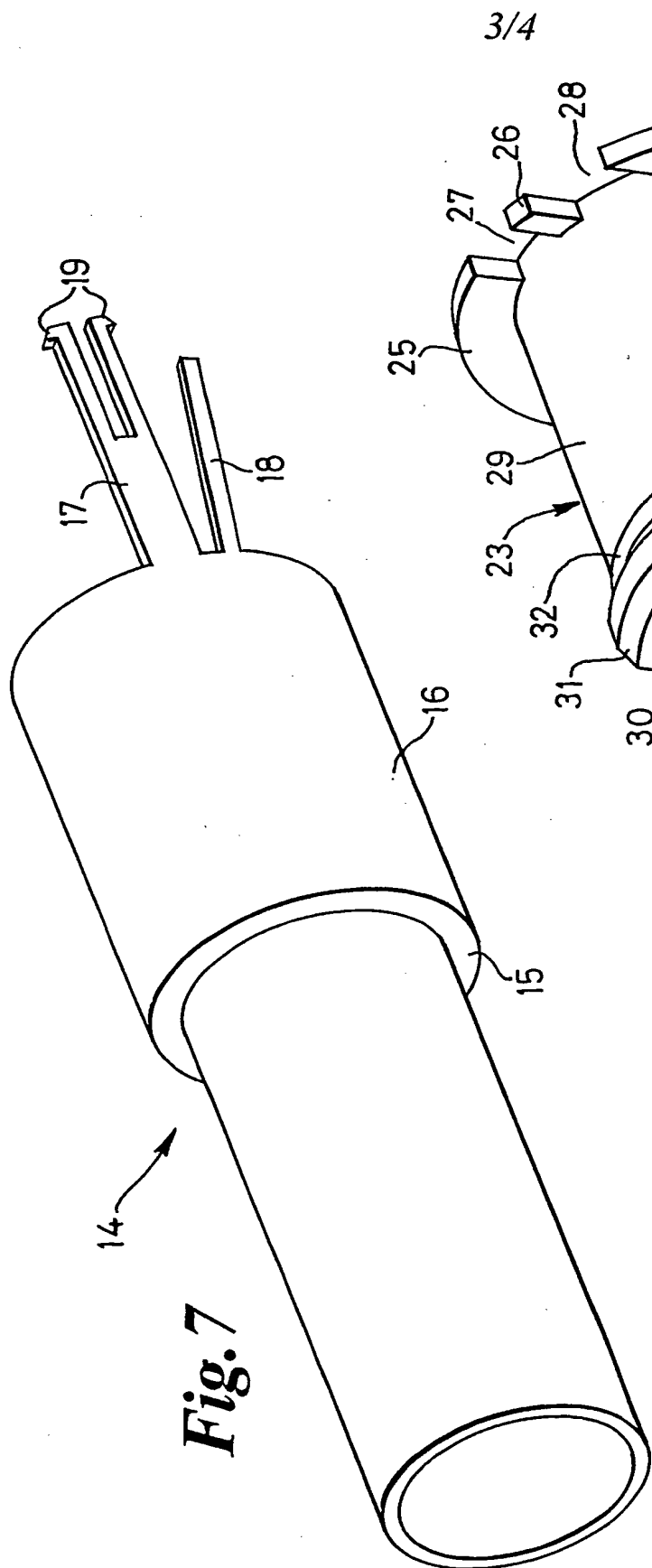


Fig. 8

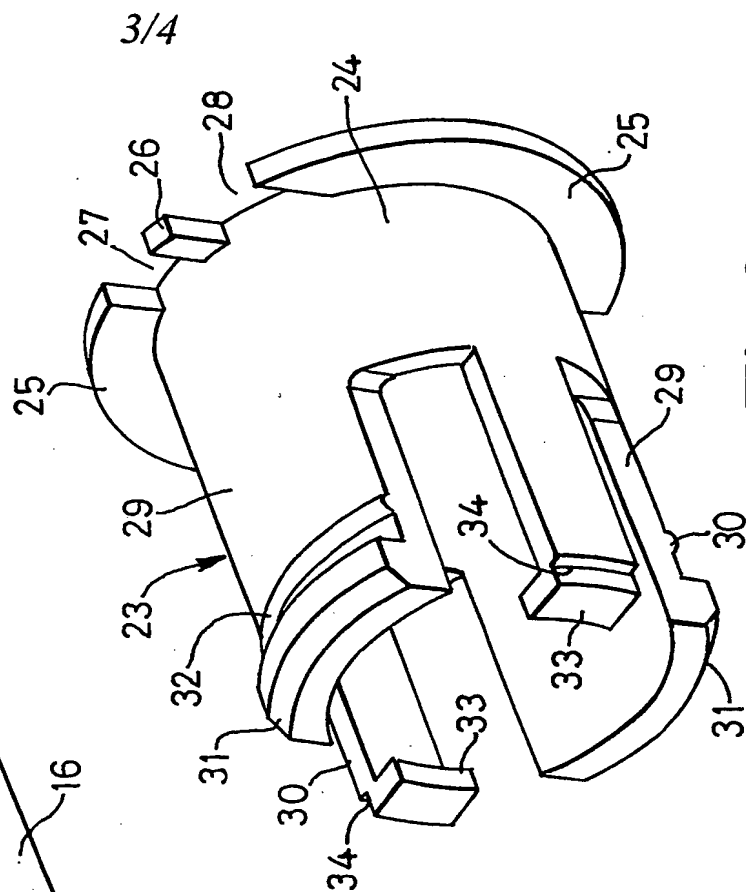


Fig. 9

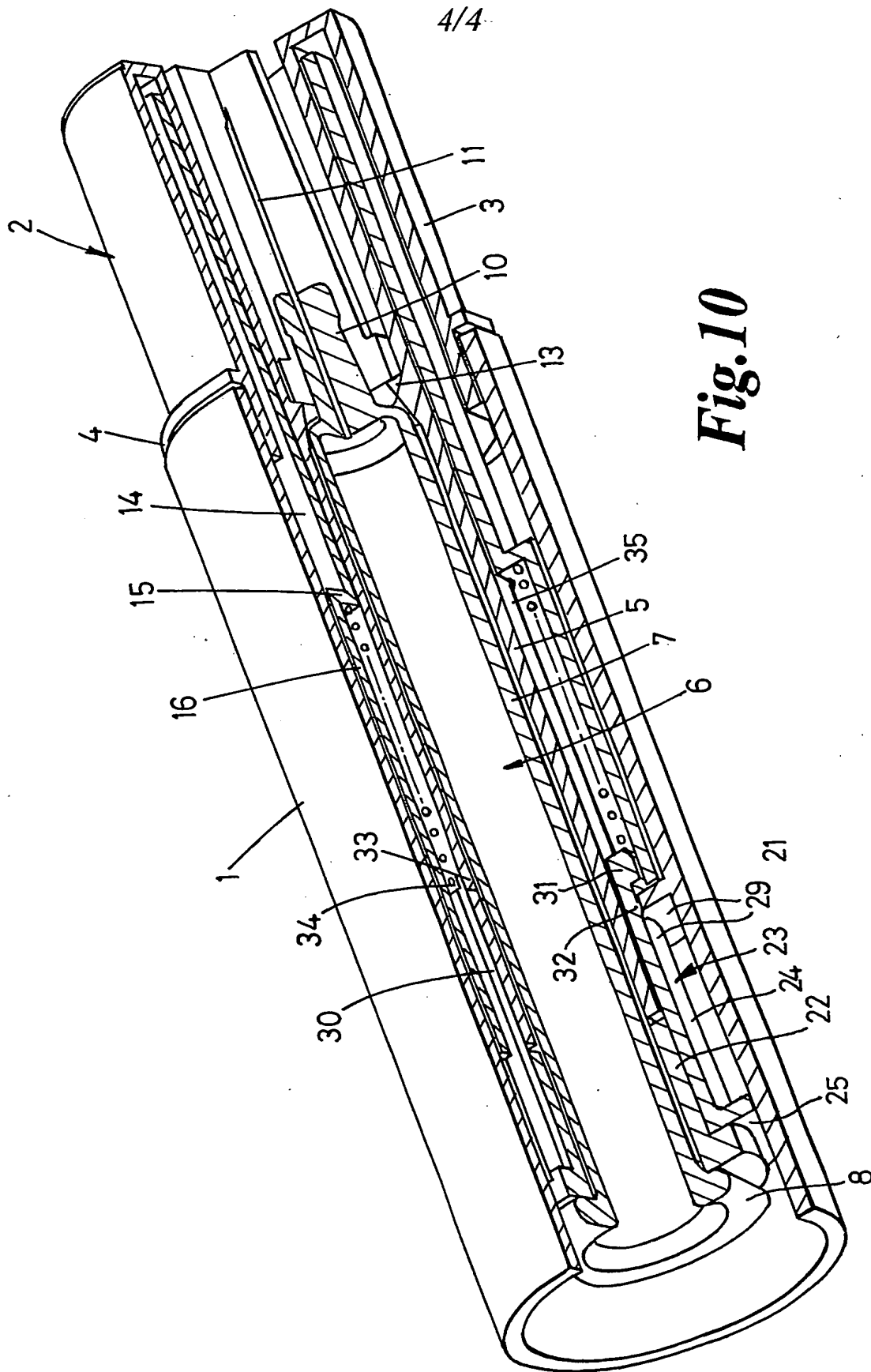


Fig. 10

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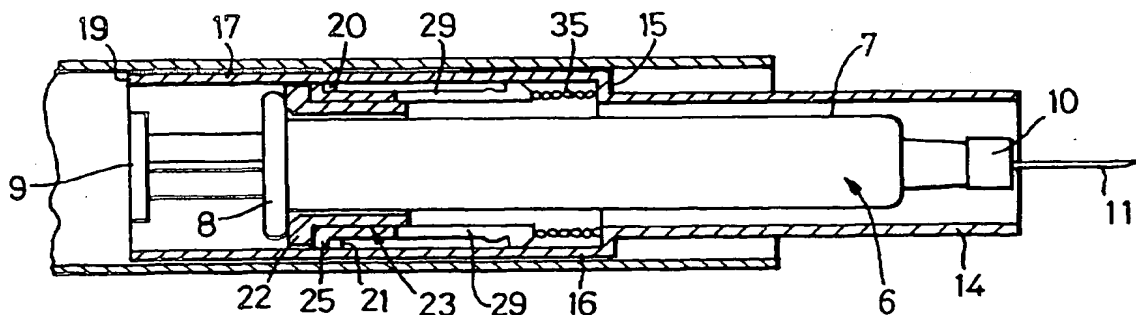
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16 October 2003

(72) Inventors; and

(75) Inventors/Applicants (for US only): MARSHALL, Jeremy [GB/GB]; 16 Cranham Street, Jericho, Oxford

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PROTECTIVE SHROUD FOR INJECTION DEVICES



(57) Abstract: When the injection device is applied to a patient's skin and a plunger (9) is pressed, the entire syringe and a carrier (23) move forwards in relation to a barrel (1), a spring (35) is compressed and a needle (11) is fully projected. Further pressing on the plunger (9) ejects the dose. The needle shroud (14) is kept at the rearward position by its firm engagement around the injection area. On withdrawal of the device, the shroud (14) is pushed forwards by the spring (35) to protect the needle (11). At the same time barbs (19) on the endsof the fingers (17) re-engage the rear end of the syringe carrier (23), whose flanges (25) are up against the rib (21), thus thwarting any attempt that may be made to pull the needle shroud clear of the barrel. The shroud (14) is therefore trapped, the needle (11) safely within.

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INTERNATIONAL SEARCH REPORT

Internat Application No
PCT/GB 02/03643A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	US 2001/056263 A1 (ALCHAS PAUL G ET AL) 27 December 2001 (2001-12-27) the whole document	1-3
X	WO 01 41841 A (CHEVALLIER STEPHANE ; PLASTEF INVESTISSEMENTS (FR)) 14 June 2001 (2001-06-14) the whole document	1, 2
A	---	3
X	FR 2 794 650 A (BRUNEL MARC) 15 December 2000 (2000-12-15)	1, 2
A	page 18, line 9-29; figures 7, 8	3
X	EP 0 966 983 A (BECTON DICKINSON CO) 29 December 1999 (1999-12-29) column 4, line 53 - column 8, line 41; figures 1-12B	1, 2

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

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O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

7 February 2003

Date of mailing of the international search report

19/02/2003

Name and mailing address of the ISA

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Jameson, P

INTERNATIONAL SEARCH REPORT

International Application No. PCT/GB 02 03643

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

Continuation of Box I.2

Claims Nos.: 12,13

The claims 12 and 13 are written in a form contrary to Rule 6.2(a) PCT.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 02/03643

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 12,13
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Internati Application No
PCT/GB 02/03643

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2001056263 A1	27-12-2001	US 6494865 B1 WO 02083205 A1 AU 6409300 A EP 1092444 A1 JP 2001137343 A US 2002156453 A1 US 2002193740 A1 US 2002193778 A1 US 2002198509 A1 US 2001012925 A1 US 2001011171 A1 US 2002068909 A1 US 2002038111 A1 US 2002045858 A1 US 2002095134 A1	17-12-2002 24-10-2002 26-04-2001 18-04-2001 22-05-2001 24-10-2002 19-12-2002 19-12-2002 26-12-2002 09-08-2001 02-08-2001 06-06-2002 28-03-2002 18-04-2002 18-07-2002
WO 0141841 A	14-06-2001	FR 2801795 A1 EP 1235603 A2 WO 0141841 A2 US 2002193746 A1	08-06-2001 04-09-2002 14-06-2001 19-12-2002
FR 2794650 A	15-12-2000	FR 2794650 A1 AU 4931300 A EP 1185323 A1 WO 0076565 A1	15-12-2000 02-01-2001 13-03-2002 21-12-2000
EP 0966983 A	29-12-1999	EP 0966983 A1 JP 11319090 A US 2002120239 A1 US 2002156426 A1 US 6319233 B1 US 2002004649 A1	29-12-1999 24-11-1999 29-08-2002 24-10-2002 20-11-2001 10-01-2002

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